

Individual Safety Report



\*3182068-6-00-01\*

MEDWATCH

ADVERSE PRODUCTS REPORTING PROGRAM

Approved by the FDA on 11/10/93

Mfr report # 8-98295-017A

UF/Dist report #

FDA Use Only

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A. Patient Information

1. Patient identifier [REDACTED]	2. Age at time of event: 62 YR or Date of birth: 10/22/1935	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
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B. Adverse event or product problem

1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death <input type="checkbox"/> life-threatening (mo/day/yr) <input checked="" type="checkbox"/> hospitalization - initial or prolonged <input checked="" type="checkbox"/> recovered	<input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other:
3. Date of event (mo/day/yr) 10/15/1998	4. Date of this report (mo/day/yr) 01/13/1999

5. Describe event or problem

OVERDOSE. Information has been received from a physician regarding a 63-year-old female patient who had been receiving Effexor (venlafaxine) 375 mg daily for approximately 18 months. Concomitant therapy included an unspecified dosage of Lortab (hydrocodone bitartrate/acetaminophen), Ativan (lorazepam) 2 mg tablets and an unspecified dosage of Tylenol (acetaminophen). Medical history included anemia (etiology unknown) treated with erythropoietin factor, and depression. Reporter suspects that the patient is taking about 850 mg more than prescribed dose over a month's time. A 30 day supply lasts about 28 days. The patient was hospitalized on 20-Oct-98 with elevated liver enzymes and ammonia levels. Follow up information was received 11-JAN-1999. The patient was hospitalized with elevated liver function tests and confusion. Effexor therapy was started OCT-1996 and was discontinued 19-OCT-1998. Concomitant therapy also included Darvocet (propoxyphene/acetaminophen) which was prescribed by another physician. The patient was over using the (Cont.)

8. Relevant tests/laboratory data, including dates

DATE	TEST	RESULT
10/20/98	SGOT	1400
10/20/98	SGPT	1800
10/20/98	Bilirubin	2.2
10/20/98	Ammonia level	53

RECEIVED  
JAN 19 1999

By

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

History of anemia, etiology unknown, treated with erythropoietin factor, peptic ulcer disease, chronic fatigue, chronic obstructive pulmonary disease, Wolfe Parkinson White syndrome, no known allergies, smoker (1/2 pack daily for 40 years), no alcohol.

DATE SENT TO FDA  
01/18/1999

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 EFFEXOR	
#2 DARVOCET (PROPOXYPHENE/ACETAMINOPHEN) TABLETS	
2. Dose, frequency & route used	
#1 over 375 mg daily ORAL	3. Therapy dates (if unknown, give duration)
#2 DOSE UNKNOWN ORAL	#1 10/00/1998 to 10/19/1998
4. Diagnosis for use (indication)	
#1 MAJOR DEPRESSION	#2 UNKNOWN
5. Event abated after use stopped or dose reduced	
#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)	
#1	7. Exp. date (if known)
#2	#2
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
See following page	

G. All manufacturers

1. Contact office - name/address (& MFG site for devices)		2. Phone number
WYETH-AYERST LABORATORIES 170 RADNOR CHESTER ROAD ST. DAVIDS, PA. 19087		(610) 902-3760
KAREL F. BERNADY, PH.D.		3. Report source (check all that apply)
4. Date received by manufacturer (mo/day/yr) 01/11/1999		<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other
5. (A)NDA # 20-151	IND #	
PLA #	pre-1938 <input type="checkbox"/> yes	
OTC product <input type="checkbox"/> yes		
8. Adverse event term(s)		
OVERDOSE LIVER FUNCTION TESTS ABNORMAL NPN INCREASED CONFUSION		

E. Initial reporter

1. Name, address & phone #	
[REDACTED] D.O. [REDACTED] Drive Suite [REDACTED] [REDACTED]	
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	
3. Occupation Physician	
4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> unk	

JAN 20 1999

Individual Safety Report



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ADJUDICATED PRODUCTS REPORTING PROGRAM

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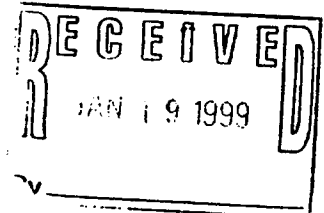
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Box B.5 - Describe Event or problem (Continuation)

Darvocet, and the physician felt the narcotic was the "most likely offender". Medical history also included peptic ulcer disease, chronic fatigue, chronic obstructive pulmonary disease, Wolff Parkinson White syndrome, no known allergies, smoking (1/2 pack daily for 40 years), and no alcohol intake. All non-essential medications were discontinued, including Effexor, the patient subsequently recovered.

Box C.10 - Concomitant medical products and therapy dates (exclude treatment of event) (Continuation)

ATIVAN (LORAZEPAM) TABLETS 2 mg daily ORAL (UNKNOWN to UNKNOWN)  
 DARVOCET (PROXYPHENE/ACETAMINOPHEN) TABLETS DOSE UNKNOWN ORAL (UNKNOWN to UNKNOWN)  
 LORTAB (HYDROCODONE BITARTRATE AND ACETAMINOPHEN) DOSE UNKNOWN ORAL (UNKNOWN to UNKNOWN)  
 TYLENOL (ACETAMINOPHEN) occasional use ORAL (UNKNOWN to UNKNOWN)



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